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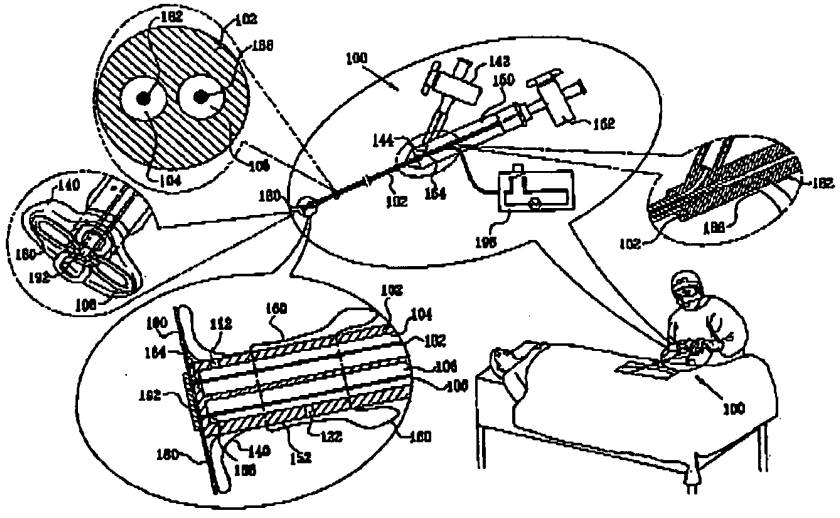
(54) Title: METHODS AND APPARATUS FOR HEMOSTASIS FOLLOWING ARTERIAL CATHETERIZATION



(57) Abstract: A hemostasis device including a shaft having a forward end, at least one anchor balloon mounted on the shaft at the forward end and at least one electrical resistance heating element, mounted on the main shaft forward of the at least one anchor element and being operable to enhance hemostasis.

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METHODS AND APPARATUS FOR HEMOSTASIS FOLLOWING ARTERIAL CATHETERIZATION

CROSS REFERENCE TO RELATED APPLICATIONS

This application is related to and claims priority of PCT Application PCT/IL2004/000100, filed February 3, 2004, the disclosure of which is hereby incorporated by reference, entitled "METHODS AND APPARATUS FOR HEMOSTASIS FOLLOWING ARTERIAL CATHETERIZATION" under CFR section 1.78 (a)(4) and CFR section 1.78 (a)(5)(i).

FIELD OF THE INVENTION

The present invention relates to catheterization systems and methodologies generally and more particularly to post-catheterization closure.

BACKGROUND OF THE INVENTION

Various techniques are known for arterial catheterization. Following arterial catheterization, it is necessary to promote hemostasis quickly and without undue hardship for the patient.

Applicant's U.S. Patents 5,728,134 and 6,048,358, and Published PCT Patent Applications WO 98/11830 and WO 00/02488 describe methods and apparatus for hemostasis that greatly simplify hemostasis and thus greatly reduce patient discomfort following arterial catheterization. These patent documents, the disclosures of which are hereby incorporated by reference, and the prior art referenced therein are considered to represent the state of the art.

SUMMARY OF THE INVENTION

The present invention seeks to provide improved systems and methodologies for post-catheterization closure.

There is thus provided in accordance with a preferred embodiment of the present invention a hemostasis device including a shaft having a forward end, at least one anchor balloon mounted on the shaft at the forward end and at least one electrical resistance heating element, mounted on the main shaft forward of the at least one anchor element and being operable to enhance hemostasis.

In accordance with a preferred embodiment of the present invention the at least one anchor element comprises an anchor balloon. Preferably, electrical resistance heating element is configured to be suitable for passage through a catheter introducer for introduction thereof to a desired hemostasis location and to be foldable over the forward end of the shaft and the at least one anchor balloon during the passage.

In accordance with another preferred embodiment of the present invention, the electrical resistance heating element is configured to be foldable over the forward end of the shaft in a manner that portions of the electrical resistance heating element generally do not overlap when so folded. Preferably, the electrical resistance heating element is configured to define a plurality of leaves. Optionally and preferably, the plurality of leaves are arranged generally in a four-leaf clover configuration.

In accordance with yet another preferred embodiment of the present invention the electrical resistance heating element is resiliently bendable to be foldable over the forward end of the shaft and to extend radially outward from the shaft prior to and following folding thereof.

In accordance with a further preferred embodiment of the present invention the hemostasis device also includes at least one peripheral balloon, disposed rearwardly of the at least one anchor balloon along the shaft.

In accordance with a still further preferred embodiment of the present invention the shaft includes at least a first lumen and a second lumen, the first lumen being operative to supply fluid to the anchor balloon for inflation thereof and the second lumen being operative to supply fluid to the peripheral balloon for inflation thereof.

In accordance with yet a further preferred embodiment of the present invention

the electrical resistance heating element is formed of foil.

In accordance with another preferred embodiment of the present invention the hemostasis device also includes a first and a second conductor operative to supply electrical power to the electrical resistance heating element, the first conductor extending through the first lumen and the second conductor extending through the second lumen.

There is also provided in accordance with a preferred embodiment of the present invention a method for accelerating hemostasis of an artery having a puncture after arterial catheterization, the method including the steps of following arterial catheterization, introducing through a catheter introducer a hemostasis device including a shaft having a forward end, at least one anchor element mounted on the shaft at the forward end and at least one electrical resistance heating element, mounted on the shaft forward of the at least one anchor balloon, such that a forward end of the hemostasis device lies exterior of the artery adjacent a puncture in a wall of the artery, accelerating hemostasis in the vicinity of the puncture by operating the electrical resistance heating element, thereby shortening the time required for hemostasis and following hemostasis, removing the hemostasis device from the patient.

In accordance with a preferred embodiment of the present invention the introducing the hemostasis device includes passing the hemostasis device through the catheter introducer including folding the at least one electrical resistance heating element over the forward end of the shaft and the at least one anchor balloon. Preferably, the folding is such that portions of the electrical resistance heating element generally do not overlap when they are folded.

In accordance with another preferred embodiment of the present invention the electrical resistance heating element is configured to define a plurality of leaves, and wherein the folding includes folding of the leaves in a generally non-overlapping arrangement. Preferably, during the folding the electrical resistance heating element is resiliently bent and folded over the forward end of the shaft and prior to and following the folding, the electrical resistance heating element extends radially outward from the shaft.

In accordance with a further preferred embodiment of the present invention the hemostasis device also includes at least one peripheral balloon, disposed rearwardly of

the at least one anchor balloon along the shaft and being arranged for operational interaction with tunica intima, tunica media and tunica adventitia portions of the artery and wherein the accelerating hemostasis includes allowing a limited volume of blood to collect outside of the artery in a region delimited by the engagement of the at least one peripheral balloon with the artery, following deflation of the anchor balloon and employing inflation of the at least one peripheral balloon to apply pressure to the artery to cause the tunica intima, tunica media and tunica adventitia portions on both sides of the puncture to be mutually engaged.

In accordance with a still further preferred embodiment of the present invention the accelerating hemostasis also includes supplying electrical power to the electrical resistance heating element which stimulates denaturation of proteins in the tunica adventitia portion, thereby causing the tunica adventitia portion to sealingly bridge the tunica media portion at the puncture. Preferably, the accelerating hemostasis includes supplying electrical power to the electrical resistance heating element for less than 5 seconds.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

Figs. 1A, 1B, 1C, 1D, 1E, 1F, 1G, 1H, 1I, 1J and 1K are simplified illustrations of a hemostasis device constructed and operative in accordance with another preferred embodiment of the present invention and various stages of its operation in a patient treatment context.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Figs. 1A, 1B, 1C, 1D, 1E, 1F, 1G, 1H, 1I, 1J and 1K, which are simplified illustrations of a hemostasis device constructed and operative in accordance with still another preferred embodiment of the present invention and various stages of its operation in a patient treatment context.

Fig. 1A shows a hemostasis device 100 for producing hemostasis following arterial catheterization, in accordance with a preferred embodiment of the present invention. The hemostasis device 100 is suitable for insertion via a conventional catheter introducer (not shown) following completion of catheterization and removal of the catheter from the catheter introducer.

In accordance with a preferred embodiment of the present invention, hemostasis device 100 comprises a main shaft 102, which has first and second lumens 104 and 106. First lumen 104 extends along the main shaft 102 to an anchor balloon inflation location 112. Second lumen 106 extends along the shaft 102 to a peripheral balloon inflation location 122.

Disposed at an end of main shaft 102 at anchor balloon inflation location 112 is an anchor element such as an anchor balloon 140. Anchor balloon 140 is selectably inflated via a stopcock 142 and associated conduit 144 in fluid communication with first lumen 104 in main shaft 102 formed in head element 150. Head element 150 is fixed to main shaft 102 at an end thereof opposite the end at which anchor balloon 140 is located.

Disposed adjacent the end of main shaft 102 in fluid communication with peripheral balloon inflation location 122, exterior of an outer wall 152 thereof, is a peripheral balloon 160. Peripheral balloon 160 is selectably inflated via second lumen 106, via a stopcock 162 and associated conduit 164 formed in head element 150.

Additionally, in accordance with a preferred embodiment of the present invention, an electrical resistance heating element 180 is disposed forwardly of the anchor balloon 140. Preferably, the resistance heating element 180 is formed of a foil which is electrically coupled at opposite ends thereof to electrical conductors which extend through the main shaft 102. In the illustrated embodiment, a first conductor 182 is attached to a first end 184 of resistance heating element 180 and preferably extends

through the first lumen 104, and a second conductor 186 is attached to a second end 188 of resistance heating element 180 and extends through the second lumen 106.

Preferably, the resistance heating element 180 has a generally four-leaf clover configuration, as shown, including radially extending leaves 190, which are preferably retained in position at the end of main shaft 102 by a retaining disc 192. Alternatively retaining disc 192 may be obviated. Electrical power is supplied to resistance heating element 180 via a switch 196, which couples first conductor 182 and second conductor 186 to a source of electrical power. Heating of resistance heating element 180 enhances hemostasis at the aperture in the artery.

Reference is now made to Figs. 1B – 1J, which illustrate various steps in a preferred mode of operation of the apparatus of Fig. 1A.

Fig. 1B illustrates the hemostasis device 100 about to be inserted into an artery 200 via a conventional catheter introducer assembly 202, following completion of a catheterization procedure and withdrawal of a catheter (not shown) from the catheter introducer assembly 202. The catheter introducer assembly 202 conventionally includes a catheter introducer sheath 204 and an entry funnel portion 205. Fig. 1B also shows in cross-section, the catheter introducer sheath 204 extending through a puncture 206 in the artery 200. It is seen that the tunica intima 208 and the tunica media 210 as well as the tunica adventitia 212 are spread apart at the puncture 206 by the presence therein of the catheter introducer sheath 204.

Fig. 1C shows the hemostasis device 100 inserted into the catheter introducer assembly 202 such that the leaves 190 are each individually folded backwards over the end of the main shaft 102 and over balloons 140 and 160 and do not generally overlap each other.

Fig. 1D shows the hemostasis device 100 inserted through the catheter introducer assembly 202 such that the outer end of the main shaft 102 extends into the artery 200 well beyond the end of catheter introducer sheath 204. As shown with particularity in Fig. 1D, at this stage both anchor balloon 140 and peripheral balloon 160 are deflated. It is seen that the leaves 190 of the resistance heating element 180 have returned to their generally planar orientation, extending radially outward from main shaft 102.

Reference is now made to Fig. 1E, which shows initial inflation of the anchor

balloon 140, preferably by use of a syringe 220, communicating with first lumen 104 via the interior of head element 150, stopcock 142 and associated conduit 144. The inflated anchor balloon 140 preferably has a cusp-type configuration.

Following inflation of the anchor balloon 140, the catheter introducer assembly 202 and the hemostasis device 100 are both withdrawn, such that the catheter introducer sheath 204 is removed from artery 200 only when the anchor balloon 140 already engages the interior wall of artery 200 in sealing engagement with the aperture in the artery 200 through which the catheter introducer sheath 204 is withdrawn and through which the main shaft 102 presently extends. This stage is shown in Fig. 1F.

As seen in Fig. 1G, initial inflation of the peripheral balloon 160 is effected, preferably by use of a syringe 240 communicating with second lumen 106 via head element 150, stopcock 162 and associated conduit 164.

Thereafter, as seen in Fig. 1H, the anchor balloon 140 is deflated, preferably by operation of syringe 220, communicating with first lumen 104 via head element 150, stopcock 142 and associated conduit 144, and the peripheral balloon 160 remains fully inflated, which preferably causes the extreme end of the main shaft 102 to be withdrawn from the artery 200 to a location lying just outside the artery wall. As seen in Fig. 1H, peripheral balloon 160 is preferably designed to allow a limited volume of blood to collect outside of the artery wall after the anchor balloon 140 is deflated. This volume of blood is located in a region, indicated by reference numeral 250, delimited by the engagement of peripheral balloon 160 with the artery wall.

It is noted that at this stage, the tunica intima 208 and the tunica media 210 as well as the tunica adventitia 212 are no longer spread apart at the puncture 206, inasmuch as the main shaft 102 is no longer present thereat and in response to pressure applied to the artery 200 by inflated peripheral balloon 160.

Preferably at this stage heating of the electrical resistance heating element 180 is effected, preferably by an operator closing switch 196, as shown in Fig. 1I. This heating preferably continues for less than five seconds.

Once acceptable hemostasis has occurred in region 250, the peripheral balloon 160 is deflated, as shown in Fig. 1J, preferably by operation of syringe 240, communicating with second lumen 106 via head element 150, stopcock 162 and associated conduit 164.

Thereafter, the hemostasis device 100 is entirely withdrawn from the patient, leaving a region 250 of hemostasis outside of artery 200, as shown in Fig. 1K.

It is noted that at this stage, by virtue of denaturation of the proteins thereof, the tunica adventitia 212 sealingly bridges the tunica media at the region of the puncture 206. Preferably, the operation of the electrical resistance heating element 180 does not produce significant heating of the tunica media and tunica intima, and does not produce heat-induced welding thereat, thus preventing the formation of lesions thereat that could otherwise occur due to excessive heating thereof.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove and shown in the drawings as well as modifications and further developments thereof which would occur to a person of ordinary skill in the art upon reading the foregoing description and which are not in the prior art.

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CLAIMS

1. A hemostasis device comprising:

a shaft having a forward end;

at least one anchor balloon element on said shaft at said forward end; and

at least one electrical resistance heating element, mounted on said shaft forward of said at least one anchor element and being operable to enhance hemostasis.

2. A hemostasis device according to claim 1 and wherein said at least one anchor element comprises an anchor balloon.

3. A hemostasis device according to either of claims 1 and 2 and wherein said at least one electrical resistance heating element is configured to be suitable for passage through a catheter introducer for introduction thereof to a desired hemostasis location and to be foldable over said forward end of said shaft and said at least one anchor balloon during said passage.

4. A hemostasis device according to claim 3 and wherein said electrical resistance heating element is configured to be foldable over said forward end of said shaft in a manner that portions of said electrical resistance heating element generally do not overlap when so folded.

5. A hemostasis device according to any of the preceding claims and wherein said electrical resistance heating element is configured to define a plurality of leaves.

6. A hemostasis device according to claim 5 and wherein said plurality of leaves are arranged generally in a four-leaf clover configuration.

7. A hemostasis device according to any of the preceding claims and wherein said electrical resistance heating element is resiliently bendable to be foldable over said forward end of said shaft and to extend radially outward from said shaft prior to and following folding thereof.

8. A hemostasis device according to any of the preceding claims and also comprising at least one peripheral balloon, disposed rearwardly of said at least one anchor balloon along said shaft.

9. A hemostasis device according to claim 8 and wherein said shaft comprises at least a first lumen and a second lumen, said first lumen being operative to supply fluid to said anchor balloon for inflation thereof and said second lumen being operative to supply fluid to said peripheral balloon for inflation thereof.

10. A hemostasis device according to any of the preceding claims and wherein said electrical resistance heating element is formed of foil.

11. A hemostasis device according to either of claims 8 and 9 and also comprising a first and a second conductor operative to supply electrical power to said electrical resistance heating element, said first conductor extending through said first lumen and said second conductor extending through said second lumen.

12. A method for accelerating hemostasis of an artery having a puncture after arterial catheterization, the method comprising the steps of:

following arterial catheterization, introducing through a catheter introducer a hemostasis device including a shaft having a forward end, at least one anchor balloon mounted on said shaft at said forward end and at least one electrical resistance heating element, mounted on said shaft forward of said at least one anchor element, such that a forward end of said hemostasis device lies exterior of the artery adjacent a puncture in a wall of the artery;

accelerating hemostasis in the vicinity of said puncture by operating said electrical resistance heating element, thereby shortening the time required for hemostasis; and

following hemostasis, removing said hemostasis device from the patient.

13. A method according to claim 12 and wherein said at least one anchor element

comprises an anchor balloon.

14. A method according to either of claims 12 and 13 and wherein said introducing said hemostasis device includes passing said hemostasis device through said catheter introducer including folding said at least one electrical resistance heating element over said forward end of said shaft and said at least one anchor balloon.

15. A method according to claim 14 and wherein said folding is such that portions of said electrical resistance heating element generally do not overlap when they are folded.

16. A method according to any of the preceding claims 12 – 15 and wherein said electrical resistance heating element is configured to define a plurality of leaves, and wherein said folding includes folding of said leaves in a generally non-overlapping arrangement.

17. A method according to any of the preceding claims 12 - 16 and wherein during said folding said electrical resistance heating element is resiliently bent and folded over said forward end of said shaft and prior to and following said folding, said electrical resistance heating element extends radially outward from said shaft.

18. A method according to any of the preceding claims 12 - 17 and wherein said hemostasis device also includes at least one peripheral balloon, disposed rearwardly of said at least one anchor balloon along said shaft and being arranged for operational interaction with tunica intima, tunica media and tunica adventitia portions of said artery and wherein said accelerating hemostasis comprises:

allowing a limited volume of blood to collect outside of said artery in a region delimited by the engagement of said at least one peripheral balloon with said artery, following deflation of said anchor balloon; and

employing inflation of said at least one peripheral balloon to apply pressure to said artery to cause said tunica intima, tunica media and tunica adventitia portions on both sides of said puncture to be mutually engaged.

19. A method according to claim 18 and wherein said accelerating hemostasis also comprises supplying electrical power to said electrical resistance heating element which stimulates denaturation of proteins in said tunica adventitia portion, thereby causing said tunica adventitia portion to sealingly bridge said tunica media portion at said puncture.

20. A method according to any of claims 12 - 19 and wherein said accelerating hemostasis comprises supplying electrical power to said electrical resistance heating element for less than 5 seconds.

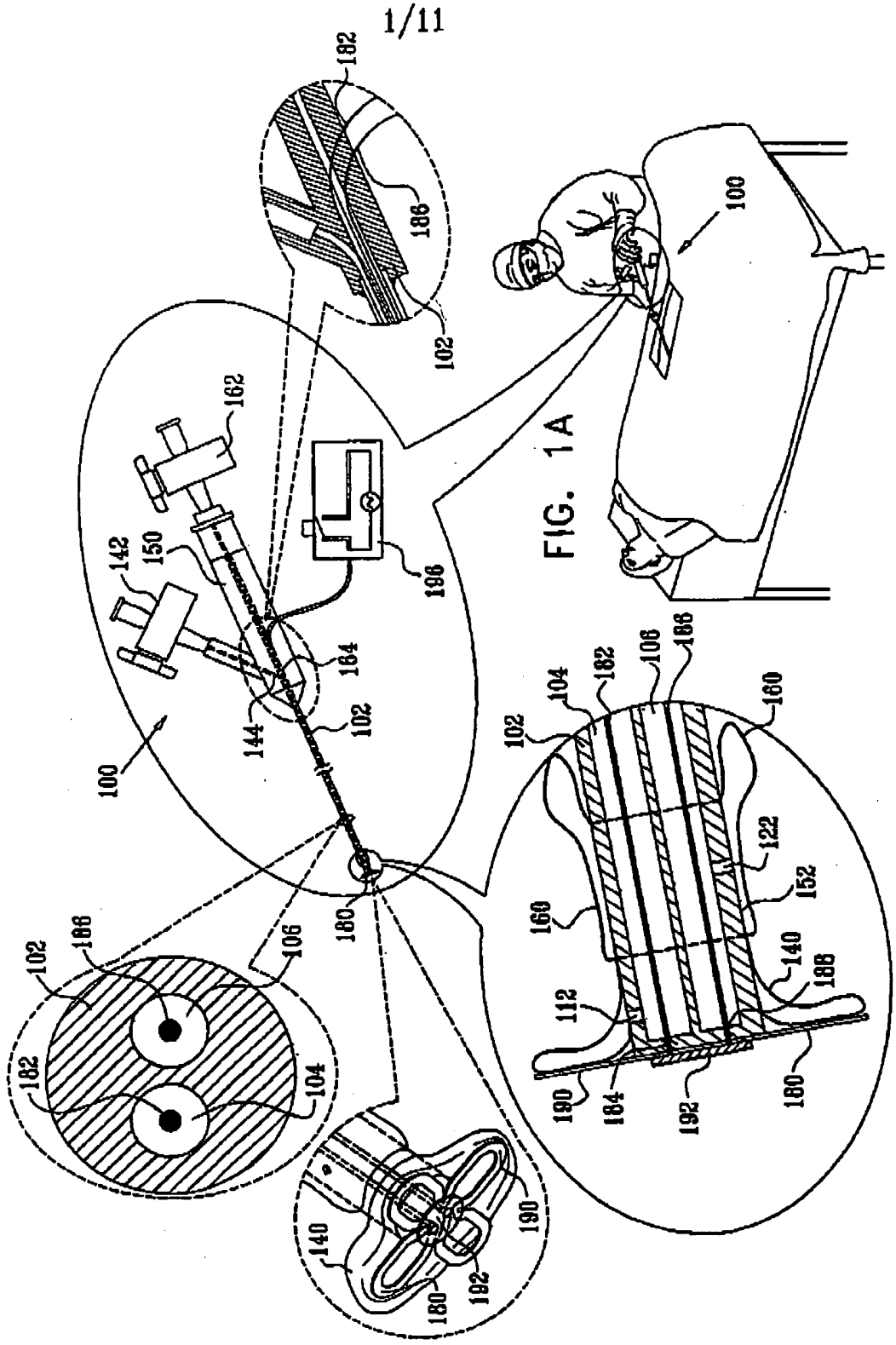


FIG. 1A

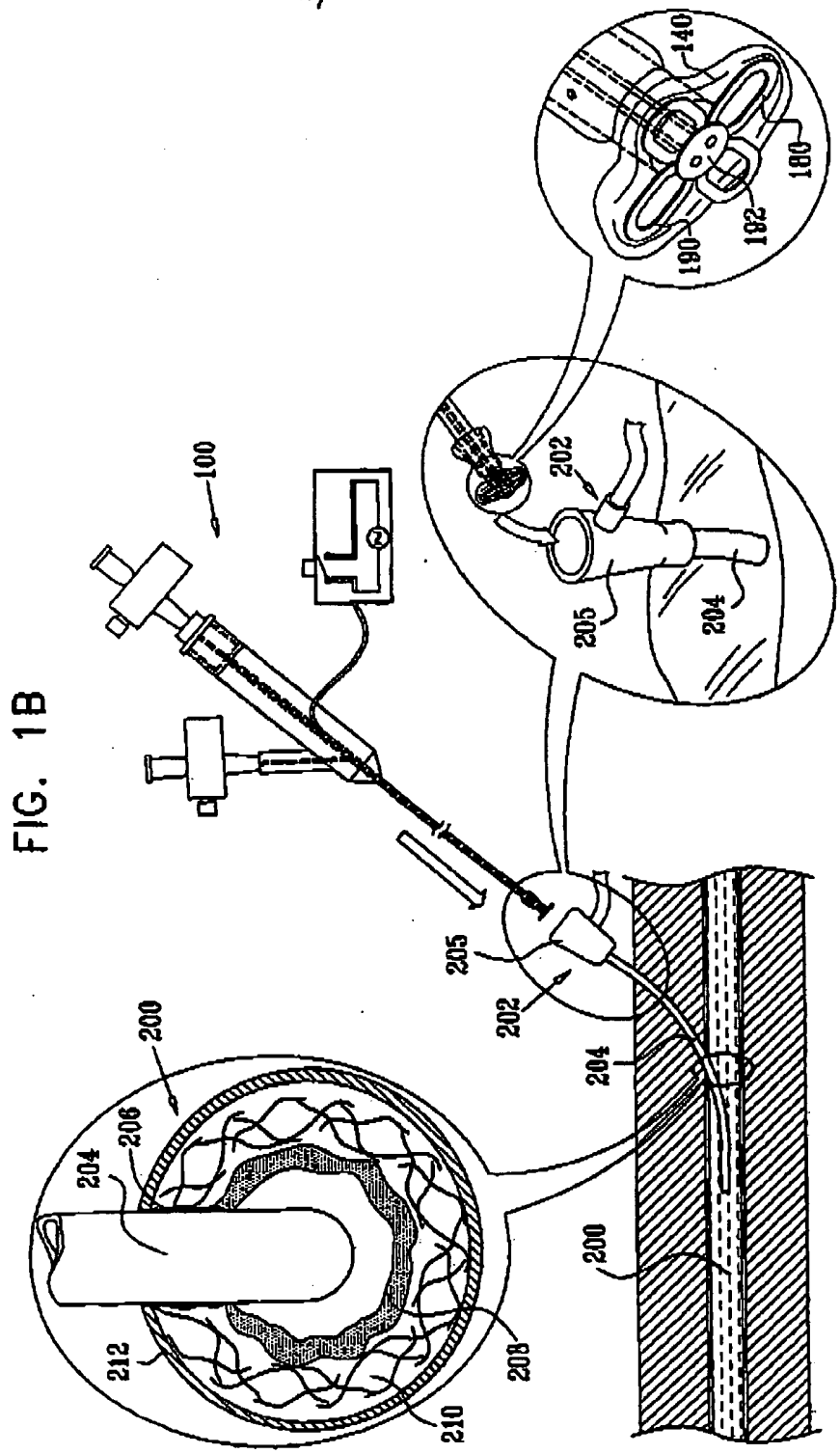


FIG. 1B

FIG. 1C

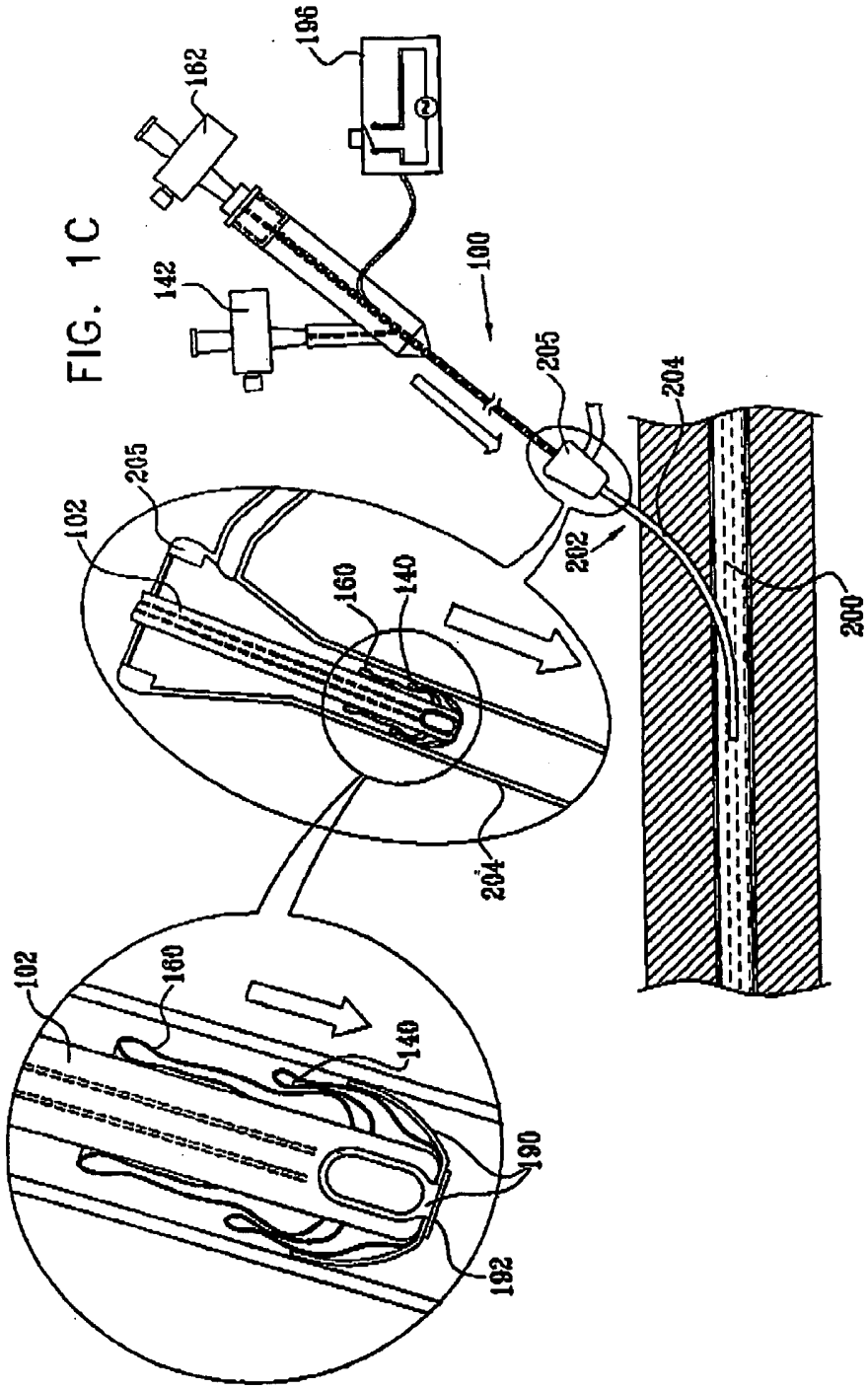


FIG. 1D

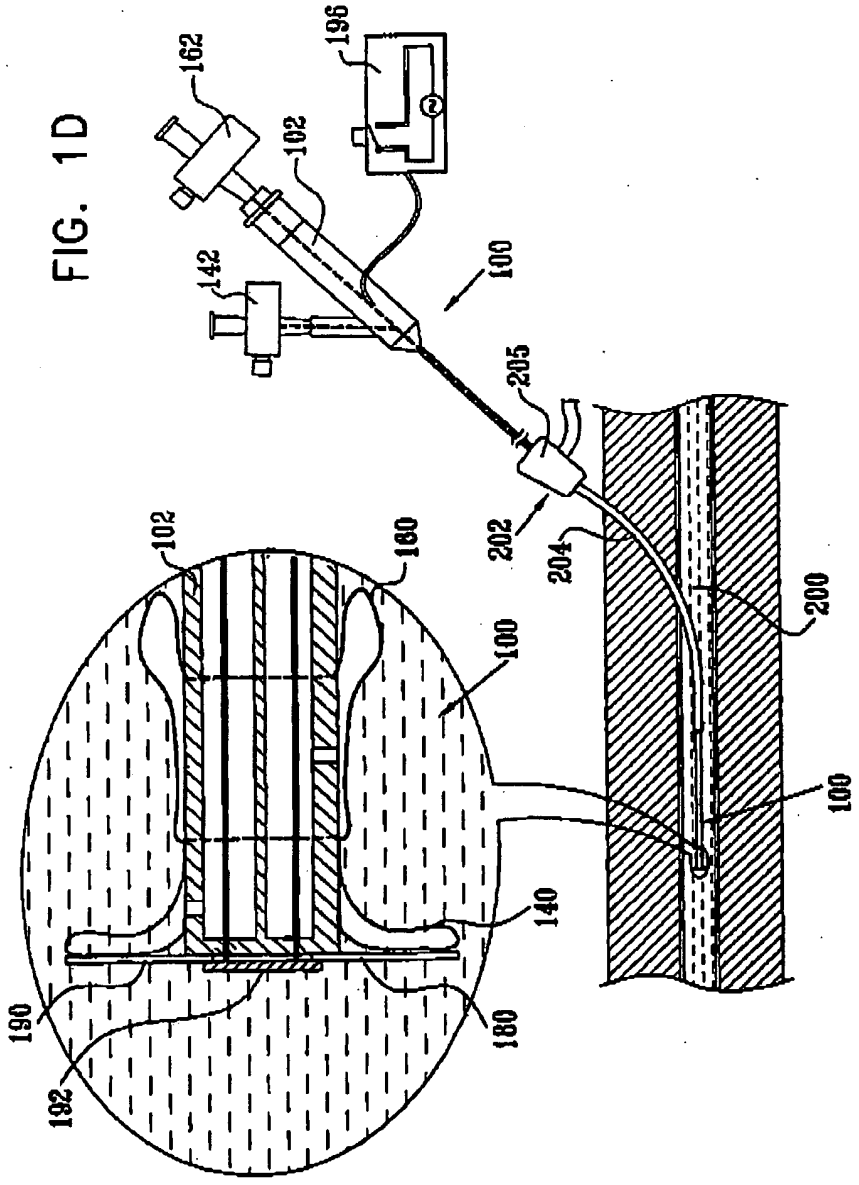


FIG. 1E

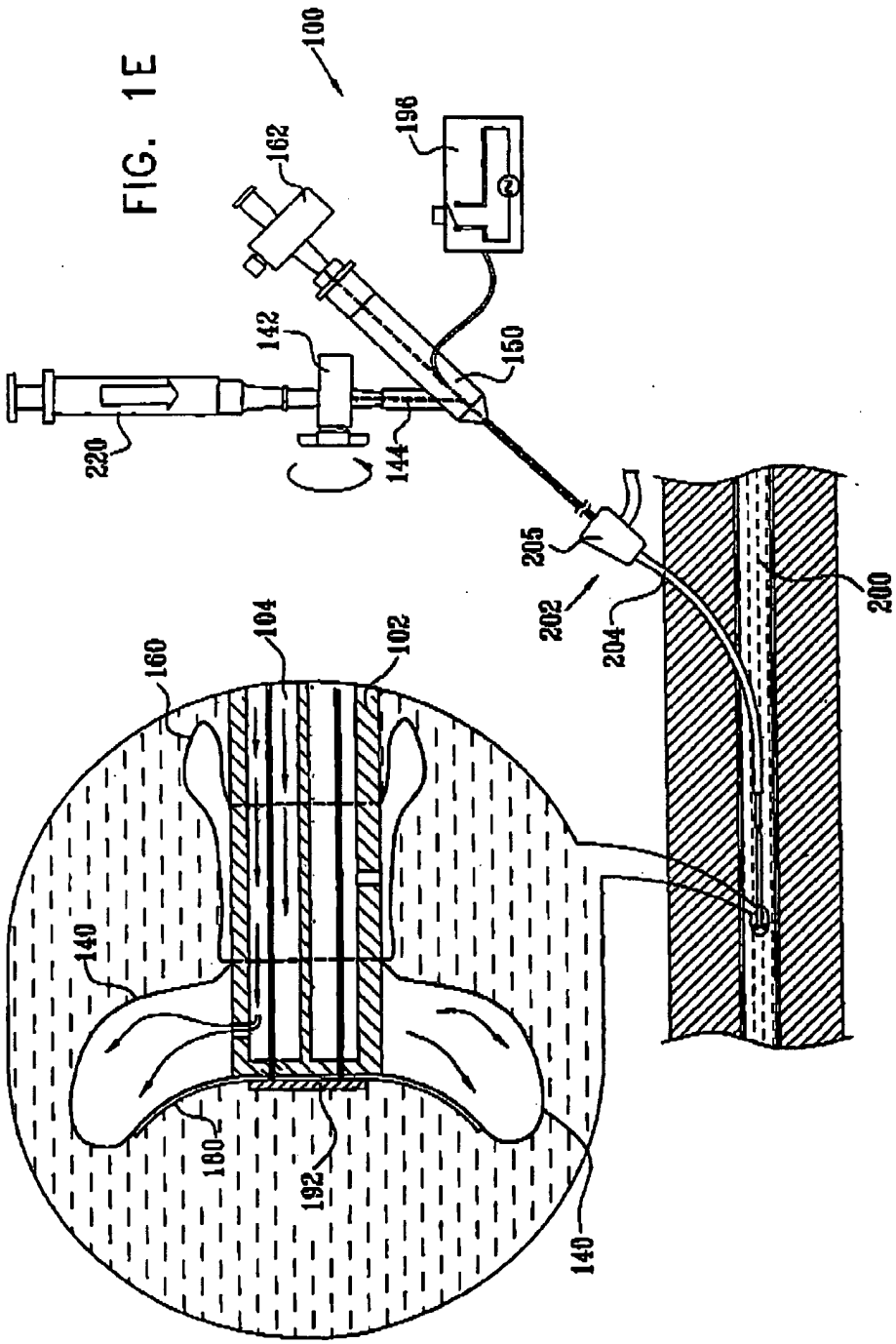
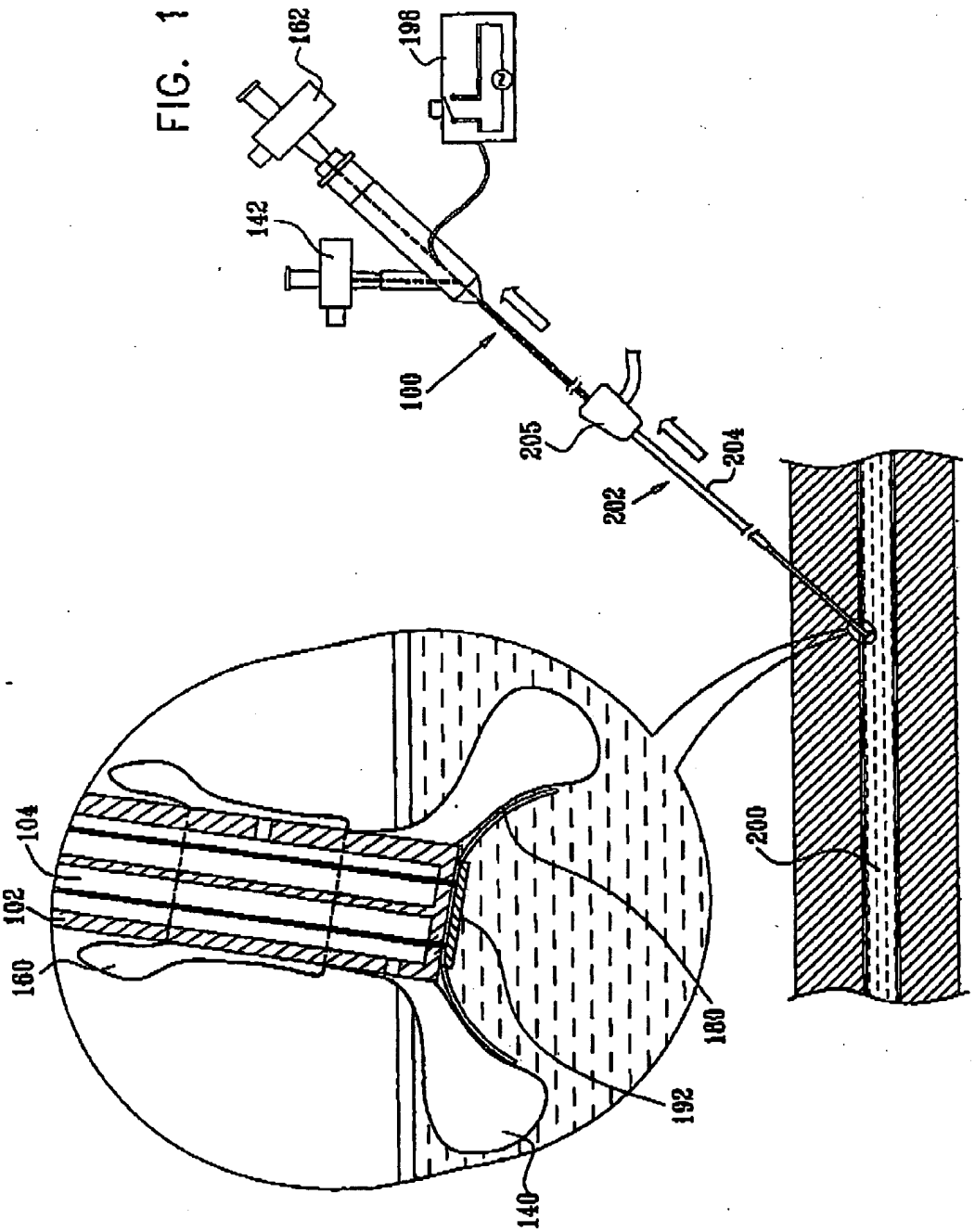


FIG. 1F



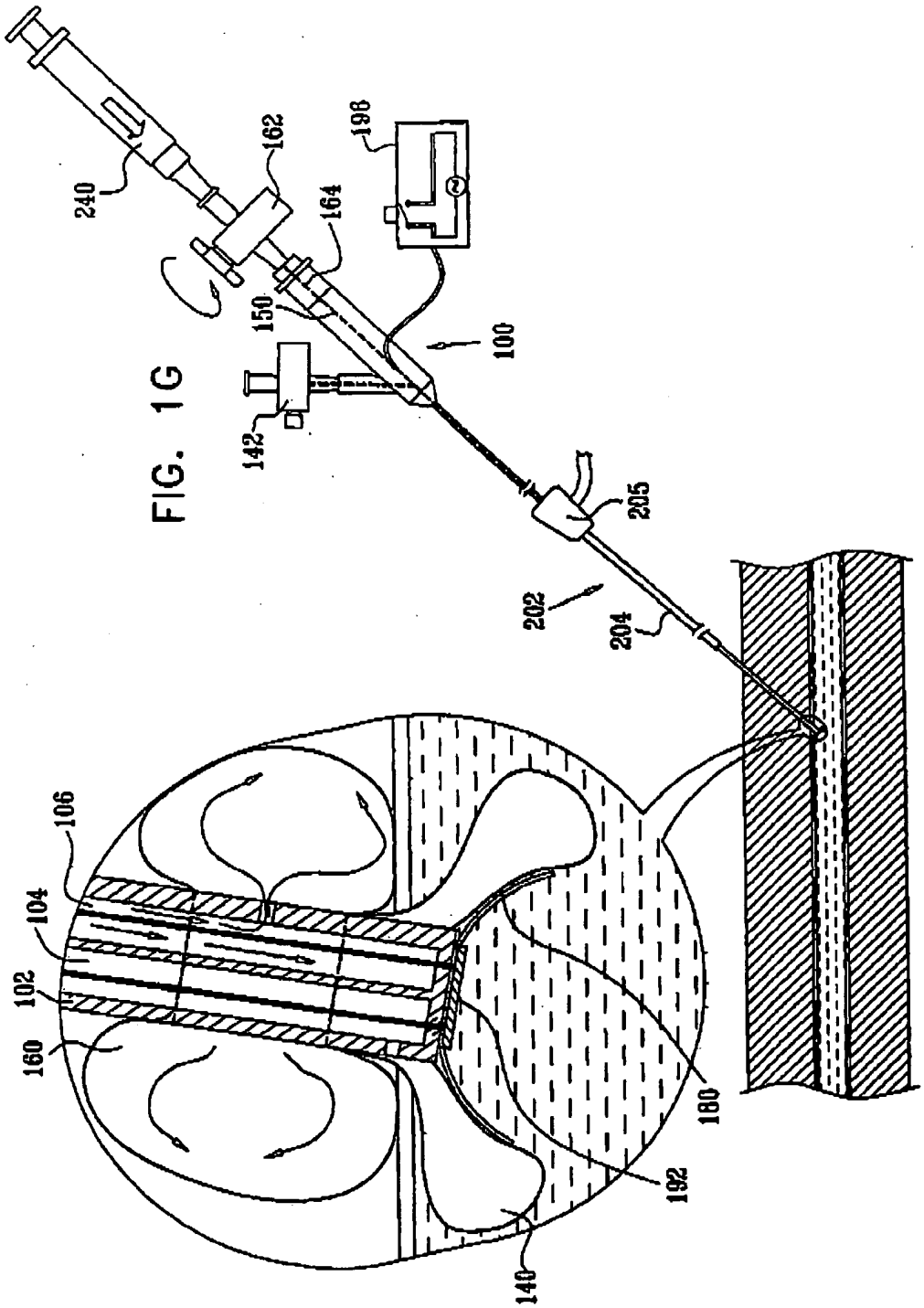


FIG. 1G

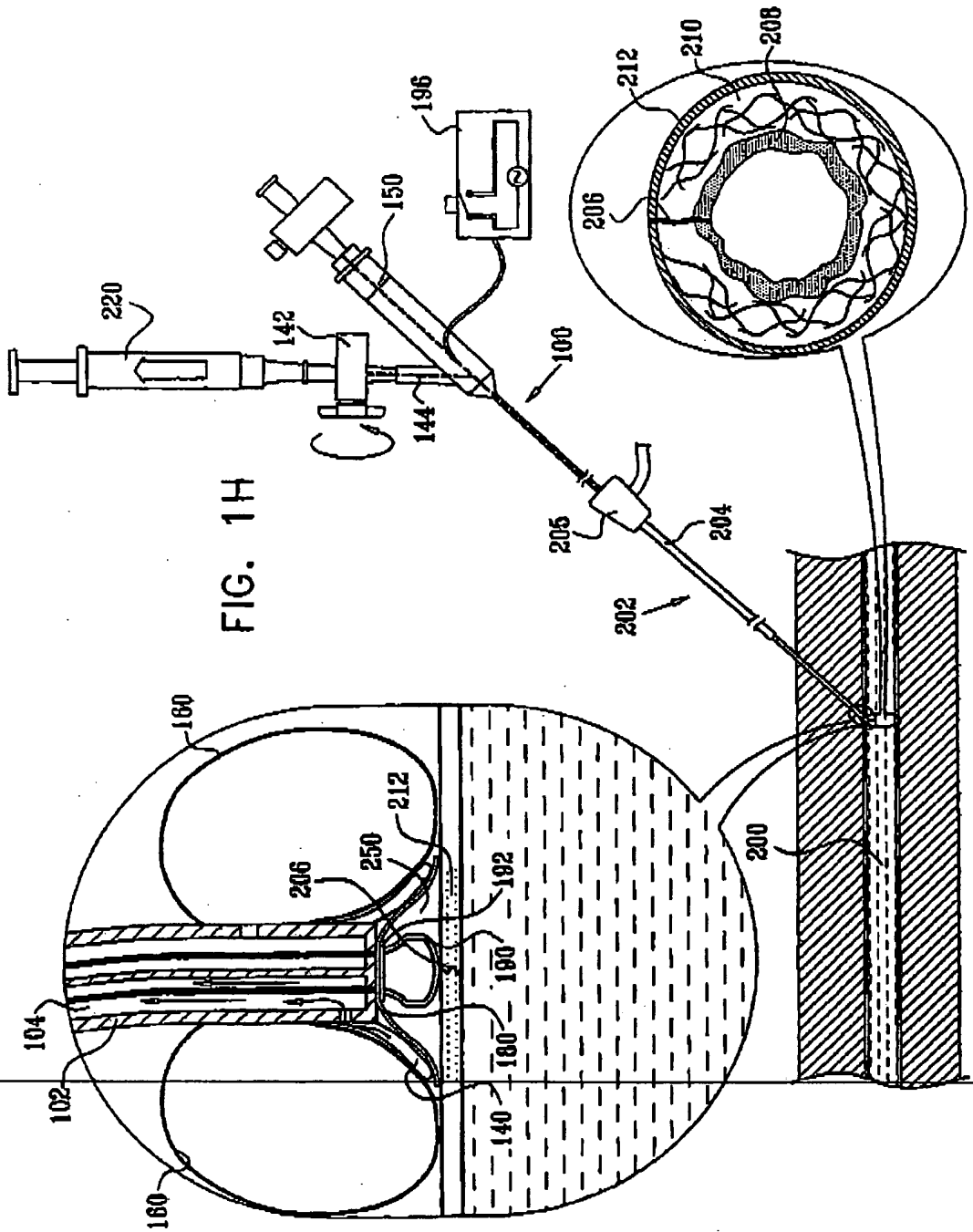


FIG. 1H

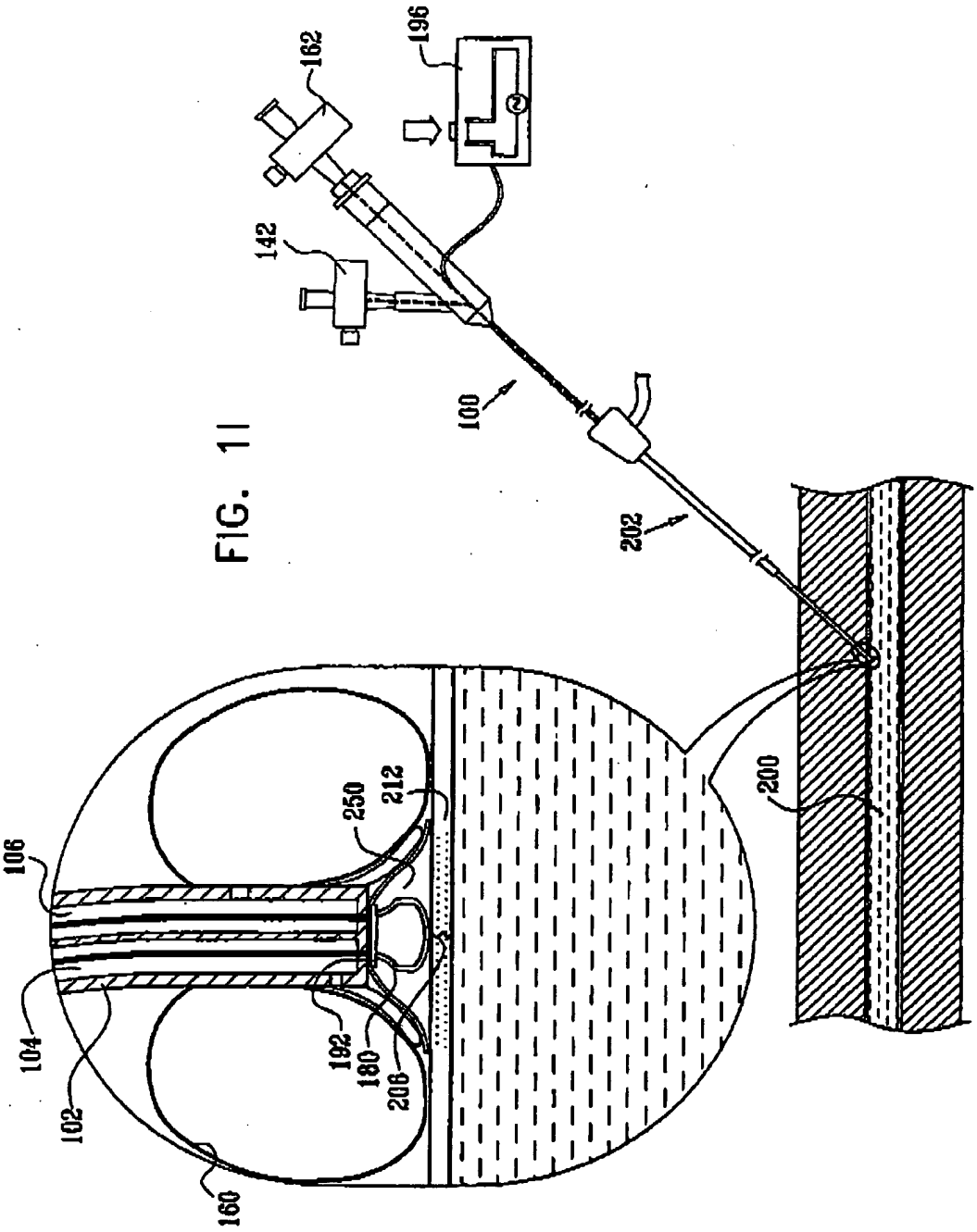


FIG. 11

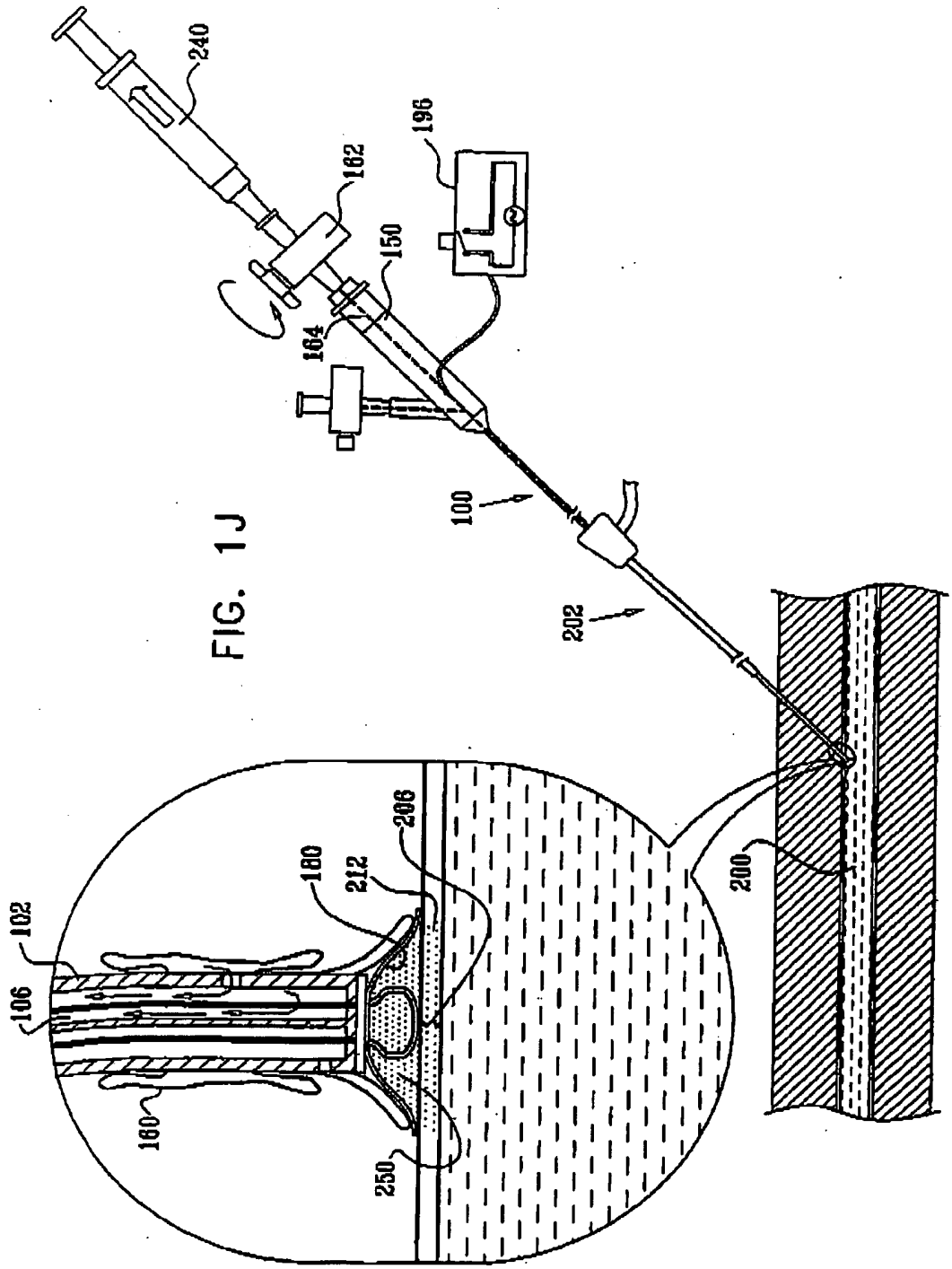


FIG. 1J

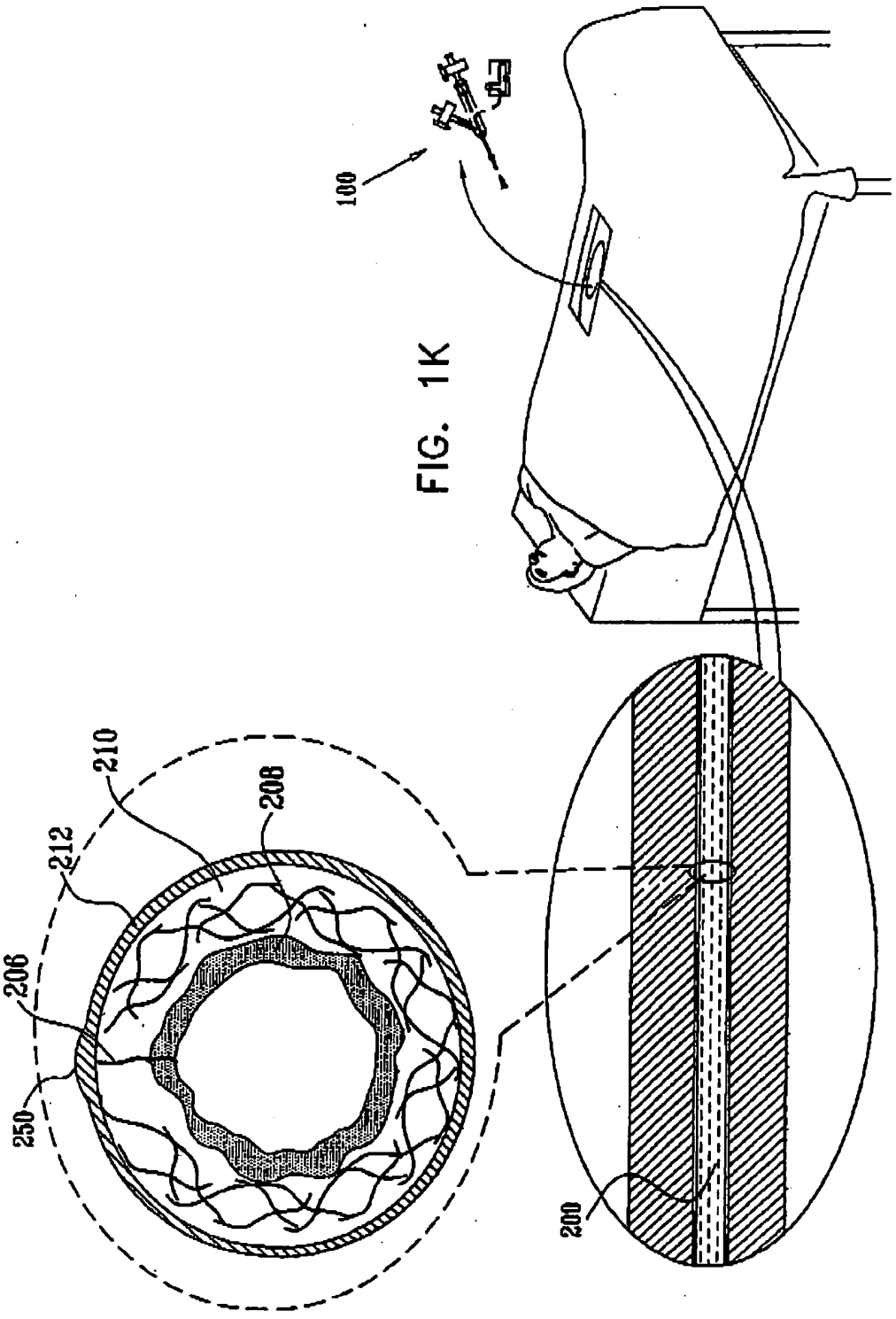


FIG. 1K